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Approved for use through 07/31/2006. OMB 0651-0031 PART & TRAPEN U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ne Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/805,099 Filing Date TRANSMITTAL March 19, 2004 First Named Inventor **FORM** Chunhui Xu, et al. Art Unit 1632 **Examiner Name** Thaian N. Ton (to be used for all correspondence after initial filing) Attorney Docket Number 099/004P Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Fee Transmittal Form Drawing(s) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a **Proprietary Information** After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Identify Terminal Disclaimer Extension of Time Request below): Request for Refund **Express Abandonment Request** CD, Number of CD(s) Information Disclosure Statement (2 pages) Landscape Table on CD Certified Copy of Priority Remarks Document(s) Form PTO-1449 (6 pages) with copies of 32 references Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Geron Corporation Signature Printed name Bart W. Wise Date Reg. No. 49,029 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: Signature

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 5 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time your course. amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date

PATENT Serial No. 10/805,099 Docket: 099/004

Information Disclosure Statement

Serial No. 10/193,884, to which this application claims priority under 35 U.S.C. §120. This is in compliance with the provisions of 37 C.F.R. §1.98(d).

This Information Disclosure Statement is not to be construed as a representation that a full search for relevant information has been made, that all relevant information has been found, or that the information provided with this Statement is considered to be material to patentability of the claimed invention as defined under 37 CFR § 1.56(b).

It is believed that no fee is required for submission of this Statement, which is filed before the first Office Action on the merits of the application. Nevertheless, should a fee be required for consideration of this Statement and the listed information, the Assistant Commissioner is authorized to charge such fee to Deposit Account No. 07-1139, referencing the attorney Docket Number indicated above.

Respectfully submitted,

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DATE: January 13, 2006

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: Chunhui Xu et al.

Art Unit: 1632

Serial No.: 10/805,099

Examiner:

**TBD** 

Filing Date: March 19,2004

Attorney Docket:

099/004

For: PROCESS FOR MAKING TRANSPLANTABLE

CARDIOMYOCYTES FROM HUMAN

**EMBRYONIC STEM CELLS** 

# INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Commissioner for Patents Arlington, VA 22313-1450

Dear Sir:

The information listed in the accompanying Form PTO-1449 and provided herewith may be material to examination of this application and is submitted in compliance with the duty of disclosure under 37 CFR § 1.56. The Examiner is requested to make this information of record in the application.

Information Disclosure

JAN 1 7 2006 (Uses Several Sheets if Necessary)

Docket: 099/004P

U.S.S.N. 10/805,099

Title: Process for Making Transplantable Cardiomyocytes from Human Embryonic Stem Cells

Inventors: Chunhui Xu, et al.

Filing Date: March 19, 2004

Group: 1632

# **U.S. Patent Documents**

Examiner Initial	Ref.	Patent No.	Filing Date	Publication Date	Class/ Subclass	Inventors	Title
/MN	A	5,733,727	Jun 7/95	Mar 31/98	435/6	Field	Myocardial grafts and cellular compositions
1	В	5,843,780	Jan 18/96	Dec 1/98	435/363	Thomson	Primate embryonic stem cells
	C	5,928,943	Nov 21/95	Jul 27/99	435/363	Franz, et al.	Embryonal cardiac muscle cells, their preparation and their use
	D	6,015,671	Nov 21/97	Jan 18/00	435/6	Field	Myocardial grafts and cellular compositions
	E	6,099,832	Jun 19/98	Aug 8/00	424/93.21	Mickle, et al.	Transplants for myocardial scars
	F	6,110,459	May 28/97	Aug 29/00	424/93.21	Mickle, et al.	Transplants for syocardial scars and methods and cellular preparations
	G	6,245,566	Mar 31/98	Jun 12/01	435/384	Gearhart, et al.	Human embryonic germ cell Line and methods of use
	Н	6,261,836	May 9/97	Jul 17/01	435/325	Cech, et al.	Telomerase
	1	6,387,369	Jul 14/98	May 14/02	424/93.7	Pittenger, et al.	Cardiac muscle regeneration using mesenchymal stem cells
	J	6,399,300	Nov 16/99	Jun 4/02	435/6	Field	Myocardial grafts and cellular compositions useful for same
	к	6,534,052	Sep 05/00	Mar 18/03	424/93.2	Xiao, et al.	Cardiac function comprising implantation of embryonic stem cell in which differntiation has been initiated
	L <sub>.</sub>	US 20050037489	Jan 20/04	Feb 17/05	435/366	Gepstein, et al.	Methods of inducing differentiation of stem cells
/MN/	М	US20050227353	Jan. 14/04	Oct 13/05	435/366	Mummery	Methods of Inducing differntiation of stem cells

# Foreign Patent or Published Foreign Patent Application

Examiner Initial	Ref.	Document No.	Publication Date	Jurisdiction	Title	Translation
/MN/	N	AU 729377	Feb 1/01	Australia	Methods and materials for the growth of primate-derived primordial stem cells in feeder-free culture	N/A
ı	Р	WO 92/13066	Aug 6/92	PCT	Mammalian cardiac myocyte cell line	N/A
	Q	WO 95/14079	May 26/95	РСТ	Myocardial grafts and cellular compositions useful for same	N/A
	R	WO 99/49015	Sep 30/99	PCT	Cardiac-derived stem cells	N/A
	s	WO 00/06701	Feb 10/00	PCT	Improvement of cardiac function by mesenchymal stem cell transplantation	N/A
/MN/	Т	WO 00/70021	Nov 23/00	PCT	Differentiated human embryoid cells and a method for producing them	N/A

Examiner	•	Date Considered
//	Marcia Noble/	03/29/2007

Information Disclosure
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(Use Several Sheets if Necessary)

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Inventors: Chunhui Xu, et al.

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Examiner Initial	Ref.	Document No.	Publication Date	Jurisdiction	Title	Translation
/MI	√ U	WO 00/78119	Dec 28/00	PCT	Cardiomyocytes with enhanced proliferative potential, and methods for preparing and using same	N/A
	٧	WO 01/22978	Apr 5/01	PCT	Autologous marrow stem cell (MSC) transplantation for myocardial regeneration	N/A
	W	WO 01/51616	Jul 19/01	PCT	Techniques for growth and differentiation of human pluripotent stem cells	N/A
	х	WO 01/53465	Jul 26/01	PCT	Human embryoid body-derived cells	N/A
	Y	WO 01/68814	Sep 20/01	PCT	Multipotent cell and cardiomyocyte cell populations, and routes to and uses of same	N/A
	z	WO 02/09650	Feb 7/02	PCT	Methods and compositions for the repair and/or regeneration of damaged myocardium	N/A
	AA	WO 02/13760	Feb 21/02	PCT	Methods and compositions for the repair and/or regeneration of damaged myocardium	N/A
	AB	WO 02/19893	Mar 14/02	РСТ	Method for the improvement of cardiac function in a living subject after myocardial infarction via intramyocardial implantation of mammalian embryonic stem cells	N/A
	AC	WO 02/30206	Apr 18/02	PCT	Genetically altered mammalian embryonic stem cells, their living progeny, and their therapeutic application for improving cardiac function after myocardial infarction	N/A
	AD	WO 03/006950	Jan 23/03	РСТ	Cells of the cardiomyocyte lineage produced from human pluripotent stem cells	N/A
/MN/	AE	WO 04/081205	Sep 23 2004	PCT	Differentiation of human embryonic stem cells to cardiomyocytes	N/A

#### **Other Documents**

Examiner Initial	Ref.	Author, Title, Source, Date
/MN/	AF	Alsan et al., Regulation of avian cardiogenesis by Fgf8 signaling, Development, 129:1935 (2002)
1.	AG	Andree et al., BMP-2 induces expression of cardiac lineage markers and interferes with somite formation in chicken embryos, Mech. of Deve., 70:119 (1998)
	АН	Antin et al., Regulation of avian precardiac mesoderm development by insulin and insulin-like growth factors, J. Cell. Physiol. 168:42 (1996)
	AI	Arai et al., Murine cardiac progenitor cells require visceral embryonic endoderm and primitive streak for terminal differentiation, Dev. Dynamics 210:344 (1997)
	AJ	Barron et al., Repuirement for BMP and FGF signaling during cardiogenic induction in non-precrdiac mesoderm is specific, transient, and cooperative, Dev. Dynamics 218:383 (2000)
	AK	Bauwens et al., Development of perfusion fed bioreactor for embryonic stem cell-derived cardiomyocyte generation: oxygen-mediated enhancement of cardiomyocyte output, biotechnology and bioengineering 90 (4):452 (2005)
	AL	Behfar et al., Stem cell differentiation requires a paracrine pathway in the heart, FASEB J, 16:1558 (2002)
/MN/	АМ	Claycomb et al., HL-1 cells: A cardiac muscle cell line that contracts and retains phenotypic characteristics of the adult cardiomyocyte, Proc. Natl. Acad. Sci. USA 95:2979 (1998)

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/Marcia Noble/	03/29/2007

Form 1449 (modified) 37 C.F.R. §1.97 Information Disclosure Statement By Applicant

(Use Several Sheets if Necessary)

Docket: 099/004P

U.S.S.N. 10/805,099

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Inventors: Chunhui Xu, et al.

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# Other Documents

Examiner Initial	Ref.	Author, Title, Source, Date
/MN/	AN	Dang et al. Controlled, scalable embryonic stem cell differentiation culture, Stem Cells, 22:275 (2004)
	AO	Doevendans et al., Differentiation of cardiomyocytes in floating embryoid bodies is comparable to fetal cardiomyocytes, J. Mol. Cell Cardiol, 32:839 (2000)
	AP	Dubus et al., Contractile protein gene expression in serum-free cultured adult rat cardiac myocytes, Pflugers Arch, 423:455 (1993)
	AQ	Fukuda, Development of regenerative cardiomyocytes from mesenchymal stem cells for cardiovascular tissue engineering, Artificial Organs 25:187 (2001)
	AR	Gepstein, Derivation and Potential Applications of Human Embronic Stem Cells, Circulation Research, 91 (10):866 (2002)
	AS	Grepin et al., Enhanced cardiogenesis in embryonic stem cells overexpressing the GATA-4 transcription factor, Development 124:2387 (1997)
	AT	Gryschenko et al., Outwards currents in embryonic stem cell-derived cardiomyocytes, Pflugers Arch. 439:798 (2000)
	AU	Heng et al., Strategies for directing the differentialon of stem cells into the cardiomyogenic lineage in vitro, Cardiovascular Research, 62:34 (2004)
	AV	Itskovitz-Eldor et al., Differentiation of Human Embronic Stem Cells into Embryoid Bodies Comprising the Three Emryonic Germ Layers, Mol. Med. 6:88 (2000)
	AW	Johansson et al., Evidence for involvement of activin A and bone morphogenetic protein 4 mammalian mesoderm and hematopoietic development, Mollecular and Cellular Biology, 15(1):141 (1995)
	AX	Kawai et al., Efficient cardiomyogenic differentiation of embryonic stem cell by fibroblast growth factor 2 and bone morphogenetic protein 2, Circ J 68:691 (2004)
	AY	Kehat e al., Electromechanical integration of cardiomyocytes derived from human embryonic stem cells, Nature Biotechnology, 22(10):1282 (2004)
	AZ	Kehat et al., Abstract, Human embryonic stem cells can diffrentiate into cyocytes with structural and functional properties of cardiomyocytes, J. Clin. Invest., 108:407 (2001)
	ВА	Kehat et al., Long term high-resolution, Electrophysiological assessment of human embryonic stem cell derived cardiomyocytes: A novel in vitro model for the human heart, Circulation, 102(18 Suppl.II):II-4 (2000)
	BB	Kessler et al., Myoblast cell grafting into heart muscle: Cellular biology and potential applications, Annu. Rev. Physiol. 61:219 (1999)
	ВС	Klug et al. Genetically selected cardiomyocytes from differentiating embryonic stem cells form stable intracardiac grafts, J. Clin. Invest. 98:216 (1996)
	BD	Koide et al., Atrial natriuretic peptide accelerates proliferation of chick embryonic cardiomyocytes in vitro, Differentiation 61:1 (1996)
	BE	Kolossov et al., Functional characteristics of ES cell-derived cardiac precursor cells identified by tissue-specific expression of the green fluorescent protein, J. Cell Biol. 143:2045 (1998)
	BF	Ladd et al., Regulation of avian cardiac myogenesis by activin/TGFB and bone morphogenetic proteins, Dev. Biology 204:407 (1998)
	BG	Lev et al., Differentiation pathways in human embryonic stem cell-derived cardiomyocytes, Ann. N.Y. Acad. Sci. 1047:50 (2005)
	вн	Liechty et al., Human mesenchymal stem cells engraft and demonstrate site-specific differentiation after in utero transplantation in sheep, Nature Med. 6:1282 (2000)
/MN/	ВІ	Li et al., Isolation of cardiomyocytes from human myocardium for primary cell culturing, J. Tiss. Cult. Meth. 15:147 (1993)

Examiner	Date Considered
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Statement By Applicant

Docket: 099/004P

U.S.S.N. 10/805,099

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	ВК	Makino et al., Cardiomyocytes can be generated from marrow stromal cells in vitro, J. Clin. Invest. 103:697 (1999)
	BL	Maltsev et al., Embryonic stem cells differentiate in vitro into cardiomyocytes representing sinusnodal, atrial and ventricular cell types, Mechanisms Dev. 44:41 (1993)
	ВМ	Matsushita et al., Formation of cell junctions between grafted and host cardiomyocytes at the border zone of rat myocardial infraction, Circulation 100[suppl. II]: II-262 (1999)
	BN	Marvin et al., Inhibition of Wnt activity induces heart formation from posterior mesoderm, Genes Dev. 15:316 (2001)
	во	McBurney et al., Control of muscle and neuronal differentiation in a cultured embryonal carcinoma cell line, Nature 299:165 (1982)
	ВР	McDowell et al., Activin as a morphogen in Xenopus mesoderm induction, Seminars in Cell & Development Biology, 10:311 (1999)
	BQ	Menard et al., Transplantation of cardiac-committed mouse embryonic stem cells to infarcted sheep myocardium: preclinical study, Lancet 366:1005 (2005)
	BR	Messina et al., Isolation and expansion of adult ardiac stem cells from human and murine heart, 95:911 (2004)
	BS	Min et al., Transplantation of embryonic stem cells improves cardiac function in postinfacted rats, J. Appl. Physiol. 92:288 (2002)
	ВТ	Monzen et al., Bone morphogenetic proteins induce cardiomyocyte differentiation through the mitogen-activated protein kinase kinase kinase Kinase TAK1 and cardiac transcription factors CsxNkx-2.5 and GATA-4, Mol. Cell Biol. 19:7096 (1999)
	BU	Muller et al., Selection of ventricular-like cardiomyocytes from ES cells in vitro, FASEB J. 14:2540 (2000)
	BV	Mummery et al., Cardiomyocyte differentiation of mouse and human embryonic stem cells, J Anat., 200 (Pt 3):233
	вw	Mummery et al., Differentiation of human embryonic stem cells to cardiomyocytes: Role of coculture with visceral endoderm-like cells, Circulation, 107:2733 (2003)
	вх	Muslin et al., WII-defined growth factors promote cardiac development in axoloti mesodermal explants, Development 112:1095 (1991)
	BY	Narita et al., Cardiomyocyte differentiation by GATA-4-deficient embryonic stem cells, Development 124:3755 (1997)
	BZ	Olson et al., Molecular pathways controlling heart development, Science 272:671 (1996)
	CA	Odorico et al., Multilineage differntiation from human embryonic stem cell lines, Stem Cells, 19:193 (2001)
	СВ	Oh et al. Cardiac progenitor cells from adult myocardium: Homing, differentiation, and fusion after infarction, PNAS 100(21): 12313 (2003)
	со	O'Shea, Embryonic Stem cell models of development, Anatomical Record, 257 (1):32 (1999)
	СС	Qin et al., Gene transfer of transforming growth factor-B1 prolongs murine cardiac allograft survival by inhibiting cell-mediated immunity, Human Gene Therapy 7:1981 (1996)
l	CD	Reubinoff et al., Embryonic stem cell line from human blastocysts: somatic differentiation in vitro, Nature Biotech. 18:399 (2000)
/MN	CE	Satin et al., Mechanism of spontaneous excitability in human embryonic stem cell derived cardiomyocytes, J Physiol 559(2):479 (2004)
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/MN/	CF	Scalia et al., Regulation of the Akt/Glycogen synthase kinase-3 axis by insulin-like growth factor-II via activation of the human insulin receptor isoform-A, J. Cell. Biochem. 82:610 (2001)
	CG	Schlange et al., BMP2 is required for early heart development during a distinct time period, Mechanisms of Development, 91:259 (2000)
	СН	Schneider et al., Wnt antagonism initiates cardiogenesis in Xenopus laevis, Genes Dev. 15:304 (2001)
	CI	Schuldiner et al., Effects of eight growth factors on the differentiation of cells derived from human embryonic stem cells, PNAS 97:11307 (2000)
	CL	Schultheiss et al., Induction of avian cardiac myogenesis by anterior endoderm, Development 121:4203 (1995)
	CJ	Schultheiss et al., A role for bone morphogenetic proteins in the induction of cardiac myogenesis, Genes & Dev. 11:451 (1997)
	СК	Shamblott et al., Derivation of pluripotent stem cells from cultured human primordial germ cells, Proc. Natl. Acad. Sci. USA 95:13726 (1998)
	СМ	Shi et al., BMP signaling is required for heart formation in vertebrates, Dev. Biol. 224:226 (2000)
	CN	Skerjane, et al., Myocyte enhancer factor 2C and Nkx2-5 up-regulate each other's expression and initiate cardiomygenesis in P19 cells, J. Biol. Chem. 273:34904 (1998)
	СР	Sugi et al., Activin-A and FGF-2 mimic the inductive effects of anterior endoderm on terminal cardiac myogenesis in vitro, Dev. Biology 168:567 (1995)
	CQ	Symes et al., Morphological differences in Xenopus embryonic mesodermal cells are specified as and early response to distinct threshold concentrations of activin, Development 120:2339 (1994)
	CR	Thomson et al., Embryonic stem cell lines derived from human blastocysts, Science 282:1145 (1998)
	cs	Velez et al., Modulationo f contractile protein troponin-T in chick myocardial cells by basic fibroblast growth factor and platelet-derived growth factor during development, J. Cardiovascular Pharmacology 24:906 (1994)
	СТ	Volz et al., Longevity of adult ventricular rat heart muscle cells in serum-free primary culture, J. Mol. Cll Cardiol. 23:161 (1991)
	CU	Walters et al., Bone morphogenetic protein function is required for terminal differentiation of the heart but not for early expression of cardiac marker genes, Mechanisms of Development, 100:263 (2001)
	CV	Wobus et al., In vitro cellular models for cardiac development and pharmacotoxicolgy, Toxic. in Vitro 9:477 (1995)
	cw	Wobus et al., Development of cardiomyocytes expressing cardiac-specific genes, action potentials, and ionic channels during embryonic stem cell-derived cardiogenesis, Ann. N.Y. Acad. Sci. 752:460 (1995)
	сх	Wobus et al., Retinoic acid accelerates embryonic stem cell-derived cardiac differentiation and enhances development of ventricular cardiomyocytes, J. Mol. Cell Cardiol. 29:1525 (1997)
	CY	Xu et al., Feeder-free growth of undifferentiated human embryonic stem cells, 19 (10): 971 (2001)
	cz	Xu et al., Characterization and enrichment of cardiomyocytes derived from human embryonic stem cells, Circulation Research, 91 (6): 501 (2002)
,	DA ,	Xu et al., Specific arrest of cardiogenesis in cultured embryonic stem cells lacking Cripto-1, Dev Biol. 196:237 (1998)
,	DB	Yatskievych et al., Induction of cardiac myogenesis in avian pregastrula epiblast: the role of the hypoblast and activin, Development, 124:2561 (1997)
/MN/	DC	Zandstra et al., Scalable production of embryonic stem cell-derived cardiomyocytes, Tissue Engineering, 9(4):767 (2003)

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	/MN/ DE Zingg et al., Genetic and epigenetic aspects of DNA methylation on genome expression, evolution, mutation carcinogenesis, Carcinogenesis 18:869 (1997)		Zingg et al., Genetic and epigenetic aspects of DNA methylation on genome expression, evolution, mutation and carcinogenesis, Carcinogenesis 18:869 (1997)	

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